

REMARKS

This responds to the Office Action dated May 18, 2007.

No claims are amended, no claims are canceled, and no claims are added. Thus, claims 1-60 are currently pending in this application. Of these 60 pending claims, claims 29-60 are currently being considered, and claims 1-28 stand withdrawn from consideration.

§103 Rejection of the Claims

Claims 29-43 and 45-60

Claims 29-43 and 45-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Marcus et al. (U.S. Patent No. 6,978,184, “Marcus”) in view of Stone et al. (U.S. Patent No. 6,280,409, “Stone”). Applicant respectfully traverses the rejection for as least the following reasons.

With respect to claim 29, Applicant is unable to find in the cited portions of the cited references, among other things, an implantable cardiac rhythm management (CRM) device including a plurality of interface channels adapted to interface with a plurality of electrodes on at least one lead, wherein the plurality of interface channels are adapted to receive sensed cardiac signals from at least one of the plurality of electrodes, as recited in the claim.

The device of Marcus senses CRT-related parameters using an external system (SCG/ECG system 32 in FIG. 2) that uses external sensors placed on a patient’s chest (column 5, line 60 through column 6, line 29). Stone does not sense CRT-related parameters, but rather senses patient activity. (see Abstract). Neither teaches or suggests an implantable CRM system with electrodes used to sense CRT-related parameters.

In addition, Applicant is unable to find in the cited portions of the cited references, among other things, an implantable cardiac rhythm management (CRM) device including a controller adapted to control processing of the sensed signals and recording of data to the memory, the data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, a

communication circuit adapted to transmit the recorded data to an external device for presentation of data trends useful to assess an efficacy of the prescribed CRT, as recited in claim 29. Marcus processes sensed signals in an external system (SCG/ECG system 32 in FIG. 2), and does not transmit recorded data to the external system from the implanted system (since the data is sensed and recorded externally).

The use of the implantable device itself to sense and record the CRT-related data is discussed in the specification: “When a patient undergoing resynchronization therapy is evaluated during follow-up, clinical symptoms or other indicia may indicate that the therapy has become less effective and that some adjustments should be made to improve the efficacy of the CRT. It may be difficult to ascertain, however, exactly what parameters should be changed in order to re-optimize the therapy. Although the operation of the implanted device may be monitored with an external programmer, some of the problems listed above may only occur intermittently or under special circumstances. It would therefore be useful for the physician to have diagnostic data that is recorded by the device during the time at which an instance of compromised resynchronization therapy occurred.” (Specification page 18, lines 18-27)

Claims 30-43 and 45-48 depend, either directly or indirectly, on claim 29 and are believed to be in condition for allowance with claim 29.

Additional reasons for allowance are found in the dependent claims. For example with respect to claim 34, Applicant is unable to find the controller adapted to record a pacing mode and time information in the memory, as recited in the claim. With respect to claim 35, Applicant is unable to find the controller adapted to record when the device is operating in an atrial tracking mode to the memory, as recited in the claim. With respect to claim 36, Applicant is unable to find the controller is adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time, as recited in the claim. With respect to claim 37, Applicant is unable to find the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time until a predetermined change occurs in delivered CRT, and then trend M samples per unit time, as recited in the claim. With respect to claim 38, Applicant is

unable to find the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time until a predetermined threshold is reached related to delivered CRT, and then trend M samples per unit time, and then trend M samples per unit time, as recited in the claim. With respect to claim 39, Applicant is unable to find the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time until a predetermined event occurs, and then trend M samples per unit time, as recited in the claim. With respect to claim 40, Applicant is unable to find the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend M samples per unit time after initiation of a trigger selected from a group consisting of: a predetermined change in delivered CRT, a predetermined threshold related to delivered CRT, and a predetermined event, as recited in the claim. With respect to claim 41, Applicant is unable to find the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend a first parameter before a trigger selected from a group consisting of a predetermined change in delivered CRT, a predetermined threshold related to delivered CRT, and a predetermined event, and to trend a second parameter after the trigger, as recited in the claim.

With respect to claim 49, Applicant is unable to find in the cited portions of the cited references, among other things, a system with a CRM device and a programmer, the CRM device including a set of interface channels adapted to provide the prescribed CRT, wherein at least one of the channels is adapted to receive sensed cardiac signals from at least one of the plurality of electrodes and a controller adapted to communicate with the set of interface channels and the memory, the controller adapted process sensed cardiac signals and to record data to the memory of the CRM device, the data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, as recited in the claim. Claims 50-53 depend directly on claim 49 and are believed to be in condition for allowance with claim 49.

With respect to claim 54, Applicant is unable to find in the cited portions of the cited references, among other things, a system with a CRM device and a programmer, the CRM device including a set of interface channels adapted to provide the prescribed CRT, wherein at least one of the channels is adapted to receive sensed cardiac signals from at least one of the plurality of electrodes, and a controller adapted to communicate with the set of interface channels and the memory, the controller adapted record data to the memory of the CRM device, the data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, as recited in the claim. Claims 55-60 depend directly on claim 54 and are believed to be in condition for allowance with claim 54.

In paragraph 2, the Office Action states: “there is no requirement that a motivation to make the modification be expressly articulated.” Applicant respectfully disagrees. “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) citing *In re Kahn*, 441 F.3d 977, 988 (CAFC 2006). To facilitate review, this analysis should be made explicit. *Id.* In the present case, Applicant respectfully asserts that one of skill in the art would not have a reason to combine the “external seismographic/ECG sensing system for CRT placement” of Marcus with the “implantable patient activity sensor” of Stone. The references are non-analogous both in placement (Stone is internal and Marcus external) and in function (Stone is diagnostic and Marcus therapeutic). In addition, there is no indication that combining Marcus and Stone would provide internal sensing of CRT-related data using a plurality of electrodes on at least one lead, as in the present subject matter.

Reconsideration and allowance of claims 29-43 and 45-60 are respectfully requested.

Claim 44

Claim 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Marcus and Stone as applied to claim 41 above, and further in view of Schroepfel et al. (U.S. Patent No. 5,749,900, “Schroepfel”). Applicant respectfully traverses the rejection for at least the following reasons.

Applicant respectfully submits that the deficiencies in the rejection of independent claim 29 with respect to Marcus and Stone discussed above are not overcome by combination with the cited portions of Schroepfel. Claim 44 depends indirectly on claim 29, and is believed to be allowable at least for the reasons provided with respect to claim 29.

Reconsideration and allowance of claim 44 are respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (715) 824-5144 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

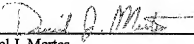
Respectfully submitted,

JOHN A. DYIACH ET AL.


By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6900

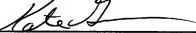
Date July 18, 2007

By / 
Daniel J. Mertes
Reg. No. 55,842

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 18 day of July 2007.



Name



Signature